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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,627

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Stephan C. F. Gamard

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

04/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,627	Applicant(s) GAMARD ET AL.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed on July 30, 2007.

Examiner acknowledges claims 50-55 are pending in this application, with claims 1-49 having been cancelled.

Claim Objections

2. Claim 50 is objected to because of the following informalities: Line 2, Applicant has not provided a structural orientation of where the "drug storage section" is located with respect to the inhaler. Line 5, "the storage section" lacks antecedent basis. Appropriate correction is required.

3. Claim 54 is objected to because of the following informalities: Line 2, Applicant has recited the pressure of the propellant gas is between about 200 psig and 50 psig. Conventionally, numeric ranges are arranged in smallest to largest numbers. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04.

Specifically, Claim 52 recites the claim limitation of "heliox...a percentage of helium equal to or greater than eighty percent (80%). Inherently, Applicant's recitation may include 100% helium; thus, making claim 52 an improperly dependent claim because it fails to further limit the subject matter of claim 51.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 50, 53 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Enfield et al. (3,874,379).

As to Claims 50, 53 and 55, Enfield discloses an apparatus wherein the recited method is inherent in the use of the apparatus. Enfield discloses an inhaler (20) including a propellant gas (delivered via the source to lines 24 and 25, Column 3, Lines 3-8) at a predetermined pressure and a drug source disposed in a drug storage section (54). As addressed by Enfield, the propellant gas is supplied to lines 24 and 25 successively with a first volume of propellant gas (via line 24) being directly directed to the spacer (31); and a second volume of propellant gas (via line 25) being directed into the drug storage section (via medicament orifice 43) to aerosolize the drug, and produce a drug cloud; and directing the drug cloud into the spacer (31). (Figure 2, and Column 4, Lines 50-65).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 51, 52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enfield et al. (3,874,379) in view of Samiotes (6,125,844).

As to Claims 51 and 52, Enfield discloses all the recited elements, yet does not expressly disclose the type of propellant gas utilized to aerosolize the medicament. However, at the time the invention was made the use of helium gas at the recited pressure was known. Specifically, Samiotes teaches the use of helium gas for the purpose of providing alternative propellant compositions for the delivery of medicament. (Column 6, Lines 20-28). Therefore, it would have been obvious to one having ordinary skill in the art at time the invention was made to modify the device of Enfield to include helium, as taught by Samiotes, to be an alternative propellant composition for the aerosolization of medicament to a patient.

As to Claim 54, Samiotes teaches the pressure of the propellant gas is reduced from 1500-3000 psi to about 25 psi. (Column 4, Lines 47-50). Yet the system of Enfield as modified by Samiotes does not expressly recite the recited propellant range. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Enfield/Samiotes to operate between

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50-200 psig provided that the propellant gas was capable of being introduced into the patient without adverse effects. Moreover, Applicant has not asserted the specific pressure ranges recited provides a particular advantage, solves a stated problem or serves a purpose different from that of providing a propellant at a safe range for the patient, thus the use of the recited range lacks criticality in its utilization. Furthermore, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the system of Enfield/Samiotes because the recited ranges to provide safe levels of pressure for the aerosolizing of medicament to the patient.

Response to Arguments

10. Applicant's arguments with respect to claims 50-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hilliard (5,586,551) and Faram (7,191,780).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

Annette F Dixon
Examiner
Art Unit 3771

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